UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Judge Patti B. Saris**
THIS DOCUMENT RELATES TO: ***State of California, ex rel. Ven-A-Care v. Abbott Laboratories, et al.*** **03-CV-11226-PBS**	

STATE OF CALIFORNIA'S OPPOSITION TO JOINT MOTION ON BEHALF OF ALL DEFENDANTS FOR A SUGGESTION TO THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION OF REMAND OF THIS ACTION TO THE CENTRAL DISTRICT OF CALIFORNIA

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INTRODUCTION

Defendants Dey, L.P. and Dey, Inc. ("Dey"), Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. ("Mylan"), and Sandoz Inc. ("Sandoz") (collectively, "Defendants")[1] have filed a motion ("Def. Rem. Mot.") (docket no. 6701) asking this Court to suggest to the Judicial Panel on Multidistrict Litigation ("JPML") that this case be remanded to the transferor court, the Central District of California.

Defendants' motion arrives at the most critical stage yet in this case. Filed on the same day as Defendants' summary judgment motions (docket nos. 6694-95, 6697-6700, 6702-11), and one day after Plaintiffs' summary judgment motions (docket nos. 6685-92), Defendants argue — seemingly oblivious to the content of their own motions — that the parties' summary judgment motions are "case specific and do not affect other coordinated cases" and "are best addressed to the transferor (trial) court." (Def. Rem. Mot. at 4.)

Defendants' motion should be denied. Remand to the Central District of California, which has no familiarity with the complex and cross-cutting (MDL 1456-wide) issues remaining to be adjudicated in this case, would be entirely inconsistent with the goals of coordinated multi-district litigation.[2] Although discovery has closed,[3] this case, for the reasons described below,

[1] Dey, Mylan and Sandoz are, effectively, the only remaining defendants in the captioned California case. A fourth defendant group, Schering Plough Inc. and Warrick Pharmaceutical Corp., has reached a settlement in principle with California under the auspices of mediator Professor Eric Green. As discussed below, California reached similarly mediated settlements with all other defendants subsequent to the Courts' order of March 22, 2007, denying Defendants' Joint Motion to Dismiss.

[2] This case was removed from state court to the Central District on March 31, 2003. On June 23, 2003, the JPML issued a conditional order transferring the case to this Court under 28 USC Section 1407, an order that became final in July. Between March 31, 2003 and July 25, 2003, the only actions taken by the Central District were purely procedural, including a transfer from Judge Tevrizian to Judge Pregerson, and orders staying all proceedings pending a decision by the JPML. (*See* Ex. 1, Civil Docket for Case # 03-CV-02238-DDP-PLA.) In other words, the transferor court has no familiarity whatsoever with the complicated issues pending in the parties' respective summary judgment motions.

[3] The discovery cutoff was June 15, 2009. There remain two pending discovery motions, both filed by Defendants in August 2009. One involves a dispute over setting an additional deposition of a Medi-Cal witness (docket no. 6394),

requires continued coordination with the other state and federal AWP fraud cases presently consolidated before this Court in MDL 1456, which presently includes three cases filed by the United States, two federal false claims act cases brought by Relator, Ven-A-Care, as well as cases brought by a number of New York counties, Iowa, South Carolina and Arizona, in addition to the class case(s).

PROCEDURAL HISTORY

In addition to Defendants' description of the procedural history of this case (Def. Rem. Mot. at 1-2), California notes that both sides filed motions for partial summary judgment, supported by, inter alia, expert witness declarations and reports, between November 24 and November 25, 2009 (coincident with the filing of Defendants' remand motion). Summary judgment briefing is due to be completed by January 29, 2010.

Significantly, as Defendants concede, it was they who first, and actively, sought the JPML's transfer of this case to this Court: "On a motion by Abbott on behalf of all defendants (including the [then] still-sealed defendants) this action was transferred by the [JPML] on June 23, 2003 to this Court for coordinated pre-trial proceedings as part of MDL 1456." (Def. Rem. Mot. at 2.) Defendants' motion seeking premature departure from this arena, just as this case reaches its most important stage, is both legally and factually deficient.

LEGAL STANDARD

Under the statute governing MDL actions and the authority of the JPML, "[e]ach action so transferred shall be remanded by the [JPML] at or before the conclusion of such pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated: *Provided, however*, That the panel may separate any claim, cross-claim, counter-

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the other a challenge to California's responses to Requests for Admission propounded by Sandoz (docket no. 6392).

claim, or third-party claim and remand any of such claims before the remainder of the action is remanded." 28 U.S.C. § 1407(a) (emphasis original).

Whether Section 1407 remand is appropriate "for an action in any particular multidistrict docket is based upon the totality of circumstances involved in that docket." *In re Managed Care Litigation*, 416 F. Supp. 2d 1347, 1348 (J.P.M.L. 2006). Although Defendants concede that the JPML "considers" the views of the transferee court (Def. Rem. Mot. at 3), that understates the importance of this Court's views on the matter. "In considering the question of remand, the Panel has consistently given great weight to the transferee judge's determination that remand of a particular action at a particular time is appropriate because the transferee judge, after all, supervises the day-to-day pretrial proceedings." *Id*. at 1348, *citing In re IBM Peripheral EDP Devices Antitrust Litigation*, 407 F. Supp. 254, 256 (J.P.M.L. 1976); *see also In re Heritage Bonds Litig.*, 217 F. Supp. 2d 1369, 1370 (J.P.M.L. 2002) (citing 28 U.S.C. § 1407) (remand is not appropriate if continued coordinated pretrial proceedings will "eliminate duplicative discovery, *prevent inconsistent pretrial rulings*, and conserve the resources of the parties, their counsel and the judiciary") (emphasis added).

Although discovery has concluded in the instant case, pretrial proceedings have not, since "pretrial, as an adjective, means before trial . . . all judicial proceedings before trial are pretrial proceedings." *In re Plumbing Fixture Cases*, 298 F. Supp. 484, 494 (J.P.M.L. 1968). This means that pretrial proceedings do not conclude until a final pretrial order is entered, and that all prior proceedings — including rulings on motions for summary judgment — are pretrial proceedings that may properly remain before the transferee court. *See Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 34 (1998) (including summary judgment motions when considering pretrial proceedings under Section 1407); *In re Patenaude*, 210 F.3d 135, 144-45 (3d

Cir. 2000) (reviewing legislative history of Section 1407 and other authorities and concluding that pretrial proceedings include summary judgment).

> Finally, it is established that [a]n MDL transferee judge has authority to dispose of cases on the merits - for example, by ruling on motions for summary judgment or trying test cases that had been originally filed in the transferee district or refiled in or transferred to that district. If summary judgment motions are pending, the transferee judge must consider whether to decide the motions or to transfer the cases back to the transferor districts. . . . *If the summary judgment motions involve issues common to all the cases centralized before the MDL court . . . the transferee judge may be in the best position to rule*.

Manual for Complex Litigation (Fourth) § 22.36 (2008) (footnotes omitted) (emphasis added).

ARGUMENT

Defendants claim that remand is appropriate because discovery has closed, and "the case will derive no additional benefit from continued coordination in the MDL 1456," purportedly because "the few remaining pretrial matters are case specific and best addressed by the trial court." (Def. Rem. Mot. at 1.) Discovery may have closed, but the other two assertions are wholly unsupported by either the facts of this case or the law.

A. This case requires continued MDL coordination based on the pendency of several "cross-cutting" issues underpinning the parties' respective summary judgment motions, and based on the importance of coordinated settlement initiatives under the auspices of the court-appointed mediator.

Several substantive issues at the core of California's AWP fraud case are precisely the same landmarks which define the terrain of cross-cutting issues characterizing the other AWP fraud cases brought by or on behalf of government plaintiffs and consolidated before this MDL Court, which include at least six other active matters. *See United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs., Inc*., 491 F. Supp. 2d 12 (D. Mass. 2007); *United States ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Dey, Inc.*, 498 F. Supp. 2d 389 (D. Mass. 2007); *United States ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Boehringer Ingelheim Corp.*, 2007 WL 4287572 (D. Mass. Dec. 6, 2007); *In re Pharm. Indus. Average Wholesale Price Litig*., 498 F.

Supp. 2d 402 (D. Mass. 2007) ("*NY Counties*"); *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Actavis Mid Atlantic LLC*, -- F. Supp. 2d -- , 2009 WL 3171798 (D. Mass. Oct. 2, 2009); *United States ex rel. Ven-A-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc.*, 2008 WL 2778808 (D. Mass. July 15, 2008).[4]

Moreover, Defendant Dey is being sued by both California and the United States, and both Dey and Mylan are defendants common to both the instant matter and the New York Counties' case.[5] Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care") is the relator common to the California and United States' cases against Dey, Roxane and Abbott in MDL 1456, and is litigating the (nonintervened) *Actavis* case on behalf of the United States against, inter alia, Defendants Mylan and Sandoz. And although it is not within the MDL, yet another case presently before this Court, with an initial trial involving two defendant groups set for February 2010, also involves pricing fraud at the expense of a state Medicaid program (albeit Wholesale Acquisition Cost (WAC) fraud). *See Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127 (D. Mass. 2008) ("*Massachusetts*"), a case in which, again, defendant Mylan is a common party.

These cases raise several significant cross-cutting issues, including (1) pharmaceutical manufacturer defendant challenges to the actionability of Medicaid claims paid under a Federal Upper Limit (FUL), (2) defendants' challenges under the rubric of "government knowledge," (3) statute of limitations defenses, and (4) the viability of intra-MDL settlement coordination and initiatives. The first three issues are integral to summary judgment motions pending in the

[4] Other cases raising substantially similar allegations of injury to state Medicaid programs caused by fraudulent AWP price reporting include *State of Iowa v. Abbott Laboratories, et. al.*, 01-CV-12257, *State of Arizona v. Abbott Labs Inc., et al.*, 06-CV-11069-PBS (master docket 01-CV-12257), and *State of South Carolina v. Abbott Laboratories, Inc.*, 06-CV-11883-PBS (master docket 01-CV-12257).

[5] Defendant Mylan is Defendant Dey's parent company. See Dey news release at http://www.dey.com/pressroom/News_010308.asp. Defendant Mylan Pharmaceuticals Inc. changed its name to "Mylan Inc." in October 2007. See http://mylan.mediaroom.com/index.php?s=43&item=317.

instant California case as well as all three federal AWP cases, and the first is also the central focus of the summary judgment motions pending before this Court in the New York Counties case. The fourth issue is central to all AWP litigation before this Court, which has consistently urged the parties to seek a mediated resolution of their claims and defenses and has been in a unique position to facilitate such resolutions because the critical parties are before this Court.

1. Federal Upper Limits ("FULs") and pricing falsity and causation.

The great majority of drugs at issue in this case (the "Subject Drugs") were reimbursed based on a FUL at least at some point during the relevant period, including 189 of the 217 (87%) Mylan National Drug Code formulations ("NDCs") at issue, 126 out of Sandoz's 149 NDCs (85%), and 20 out of Dey's 28 NDCs (71%). Defendants first raised the issue of FULs in their motions to dismiss, arguing there could be no causation on claims paid at a FUL, an argument this Court rejected. *See In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d 164, 180 (D. Mass. 2007) ("*California*"). They have raised that issue again in their summary judgment motions.

Echoing summary judgment arguments jointly raised by them in the New York Counties case, Dey, Mylan and Sandoz, have attacked the integrity of the federal process by which FULs were determined and set, and have additionally asserted that California cannot establish causation and falsity as to FUL-paid claims. The intricacies of the FUL process and the respects in which the FUL claims asserted by California differ from those asserted by the New York Counties are perfect examples of the reasons why this case should remain before this Court. Unlike the New York Counties, California simply seeks to recover for products paid at a FUL where under California's "lesser of" adjudication formula, the State would have reimbursed for Defendants' products based on their AWPs had they reported honest prices.

Plaintiffs and defendants in the New York Counties case have both filed motions for summary judgment in which they defend or challenge various attributes of the process by which the federal Centers for Medicare and Medicaid Services ("CMS") determines FULs for certain drugs. (*See* Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Judgment on Issues Relating to the Federal Upper Limit and Under New York Social Services Law§ 145-B (docket no. 6059); Defendants' Memorandum in Support of their Joint Motion for Summary Judgment on Plaintiffs' "FUL Fraud" Claims (docket no. 6053).) All three of the California Defendants — Dey, Mylan and Sandoz — are defendants in the New York Counties case, and in particular as to claims paid by the New York Counties at a FUL.[6] The Court also directed the United States to provide supplemental briefing on the Federal Upper Limit, which it filed on November 25, 2009 (Supplemental Brief of United States on the Federal Upper Limit (docket no. 6693)). The Court has not issued a ruling in the New York Counties summary judgment motions.

All three Defendants have raised substantially similar arguments (regarding the process by which CMS determined the FUL for drugs) in their summary judgment motions in the instant case. Defendants' summary judgment motions in both the New York Counties and California cases rest in significant part on testimony elicited from CMS personnel. (*See* Defendants' Memorandum in Support of their Joint Motion for Summary Judgment on Plaintiffs' "FUL Fraud" Claims (docket no. 6053) (New York Counties case); Defendants' Joint Brief in support of Their Motions for Summary Judgment (docket no. 6710) at 26-29, in the instant case, and Defendants' corresponding Joint Statement of Undisputed Facts (docket no. 6703), numbers 69-

[6] *See* Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Judgment on Issues Relating to the Federal Upper Limit and Under New York Social Services Law § 145-B, docket 6059, at 1, n. 3.

100.[7]) Although California contends that many of Defendants' FUL arguments do not apply here, there is no question that these cases raise complex and overlapping issues that require resolution by this Court in the interests of judicial economy and avoiding inconsistent rulings.

Furthermore, Dey has raised precisely the same factual and legal arguments in its summary judgment motion in the United States' case with respect to claims for all Dey drugs at issue which were paid at a FUL by any and all state Medicaid programs (including California's). (*See* Dey's Memorandum of Law in Support of Motion for Partial Summary Judgment (docket no. 6194) at 35.)

In sum, California's case against Dey, Mylan and Sandoz is characterized by the critical fact that the majority of each Defendant's NDCs were paid under a FUL at one or more times from 1994-2004. Dey, Mylan and Sandoz have filed joint and individual motions for summary judgment in the California case which include the assertion that there can be no liability for any claims paid under a FUL. The factual and legal basis for those arguments closely overlap with arguments raised in summary judgment motions also pending before this Court in the New York Counties' and United States' cases. The imperative for this Court to adjudicate the question of the viability of FUL-paid claims by the various MDL 1456 government plaintiffs now constitutes a quintessential and complex "cross-cutting" MDL 1456 issue. This inescapably demolishes Defendants' central claim that remand is warranted because the issues remaining in this case are "case specific and are uniquely suited to adjudication by federal courts sitting in the state of California." (Def. Rem. Mot. at 4.)

[7] All three Defendants further incorporate the arguments raised in their Joint Brief in their individual motions for partial summary judgment.

2. Government Knowledge and Scienter

The primary defense raised by the California Defendants, as in all of the AWP fraud cases in MDL 1456 involving government plaintiffs, is that of "government knowledge." This defense constitutes another cross-cutting issue throughout those government cases which involve common defendants, common programs, and common drugs. As to one defendant common to the United States and California cases, there is substantial overlap between (a) time periods (1992-2008 for the United States case as to California Medicaid, compared to 1994-2004 for the California case), and (b) the drugs at issue (see Exhibit 2, depicting 20 NDCs which are common to the United States and California cases (20 of the United States' 26 Dey NDCs are also California Dey NDCs)).

In particular, in their pending motions for partial summary judgment in the instant California case, Dey, Mylan and Sandoz each claim that various state and federal government documents and pieces of deposition testimony constitute evidence of "government knowledge" sufficient to negate the requisite scienter on their part. (*See* Defendants' Joint Brief in support of Their Motions for Summary Judgment (docket no. 6710) at 21-24 (an argument further incorporated by reference in each Defendant's individual motion for partial summary judgment).) Defendants' motions for partial summary judgment in the instant case rely heavily on the testimony of key federal officials (former CMS Administrators), reports issued by the Office of Inspector General for the United States Department of Health and Human Services ("HHS-OIG"), HHS-OIG meetings and correspondence with various state officials, and the testimony of various federal and state Medicaid officials, including key Medi-Cal officials such as Kevin Gorospe, in attempting to support their government knowledge argument. (*See* Defendants' Joint Statement of Undisputed Facts ("SOF") (docket no. 6703) SOFs 3, 6-9, 14, 22-

58.) Defendant Dey relies even more heavily on a litany of federal OIG reports and studies in its individual Statement of Undisputed Facts (in support of its motion for partial summary judgment in the instant case (docket no. 6695) (all of which are also central to its government knowledge defense in the parallel case against Dey brought by the United States), as demonstrated in SOFs 18-26, 40.

Moreover, in the United States' cases against Dey, Abbott, and Roxane, defendants have filed joint and individual motions for summary judgment which rely on substantially identical federal and California (and other state) materials in arguing for summary judgment with regard to the California portion of the United States' case as it concerns Medicaid. (*See* Defendants Abbott Laboratories, Inc., Dey, Inc., Dey, L.P., Dey L.P., Inc., and Boeheringer Ingelheim Roxane, Inc., and Roxane Laboratories, Inc.'s Combined Local Rule 56.1 Statement of Additional Material Facts Pertinent to the United States' Motions for Partial Summary Judgment Against Defendants (docket no. 6439).) These SOFs are extensively punctuated with extracts from the deposition testimony of key California Medicaid officials (almost all of it taken by Defendants in the course of the California case), or extracts of California-specific state agency documents. (*See, e.g.*, SOF 1 (Medi-Cal official Gorospe's deposition ("dep."), 19 (same), 37 (extract from California State Plan), 49 (extracts from a California cost survey), 53 (same), 58 (dep. testimony of Medi-Cal officials Rosenstein and Walker, in addition to more from Gorospe), 59 (OIG study), 75 (more Gorospe dep.).) Dey similarly exhibits reliance on the same type of evidence in its individual Concise Statement of Undisputed Material Facts in Support of Dey, Inc. and Dey L.P., Inc.'s Motion for Partial Summary Judgment (in the United States' case against Dey) (docket no. 6190). (*See, e.g.*, SOF 156 (Medi-Cal official Len Terra dep.), 235, 237, 251, 271, 279 (Gorospe dep.), and 273 (extract from California State Plan).)

In denying Defendants' motions to dismiss this case, this Court determined that the issue of government knowledge "presents a difficult legal question. . . . As California alleges it did not know the extent of false drug prices, or approve them, dismissal is inappropriate." *California*, 478 F. Supp. 2d at 174. As the preceding discussion makes clear, both the United States' and California's cases feature aggressive government knowledge defenses by Defendants (themselves common to both cases) and featuring extensive reliance on testimony and documents originating within federal and state agency records, and agency officials' testimony. The critical issues of the extent to which Defendants may avail themselves of a government knowledge defense, and, if so, whether the evidence in the record is sufficient to satisfy their burden has become so inextricably woven into the fabric of the California and United States' cases (as well as the New York and (non-MDL) Massachusetts cases, that this Court's adjudication of those issues is vital to the orderly and coherent pre-trial management of California's case against Dey, Mylan and Sandoz. In short, Defendants' claim that the remaining pre-trial issues in the California case are "case specific and are uniquely suited to adjudication by federal courts sitting in the state of California" (Def. Rem. Mot. at 4) is, under these facts, patently ludicrous.

3. Statute of Limitations Issues.

In their pending motions for partial summary judgment in the instant case, Defendants Mylan and Sandoz assert defenses grounded in the limitations periods defined under the CA FCA (Cal. Gov't Code § 12654). Their arguments rest on claims as to the timing and content of relator Ven-A-Care's disclosures to California, as well as other alleged sources of information supposedly sufficient to put the state on notice for time-bar purposes. (*See* Defendant Mylan Inc. and Mylan Pharmaceutical Inc.'s Brief in Support of Their Motion for Partial Summary

Judgment (docket no. 6708) at 2-5, and Defendant Sandoz Inc.'s Brief in Support of its Motion for Summary Judgment (docket no. 6697) at 9-12.)

Both Mylan and Sandoz rely on documents allegedly associated with Ven-A-Care's disclosures to California, and the alleged import of various federal OIG studies. (*See* Defendants' Joint Statement of Undisputed Facts ("SOF")(docket no. 6703), SOFs 29-32, 60-63; Local Rule 56.1 Statement of Undisputed Facts in Support of Defendant Sandoz Inc.'s Motion for Summary Judgment (docket no. 6698) (same).) Defendant Dey, in the United States' case, has raised a statute of limitations defense resting in part on the same evidence, i.e. the timing and content of Ven-A-Care's disclosures to the government, and the extent to which federal OIG studies allegedly put the government on notice of Dey's fraudulent AWPs. (*See* Dey's Memorandum of Law in Support of Motion for Partial Summary Judgment (docket no. 6194) at 21-25.)

As this Court has previously held, statute of limitations defenses raise fact intensive issues, such that "[t]he Court will have to address the statute of limitations — what the government should have known, and when it should have known it — *drug-by-drug*." *Massachusetts*, 608 F. Supp. 2d at 160 (emphasis added). Thus, the statute of limitations arguments before this Court also represent cross-cutting issues intersecting the California and United States cases on at least four substantive planes: a) the substantial overlap between California's and Dey's drugs (*see* Exhibit 2), b) the fact that the United States is suing for losses incurred in its federal share of California's Medicaid program at 40-44), c) because the Defendants rely on many of the same documents and testimony; and d) because the United States and California cases are jointly shaped and characterized by the fact that Ven-A-Care is the common relator.

Again, Defendants' claim that the remaining issues now pending before this Court at this critical pre-trial stage in the California case are "case specific and are uniquely suited to adjudication by federal courts sitting in the state of California" (Def. Rem. Mot. at 4) is wholly inconsistent with the facts.

4. Settlement Coordination

This Court has repeatedly stated its concern that all parties in MDL 1456 (as well as those in related non-MDL litigation) make every appropriate effort to pursue a mediated settlement. The Court held a hearing on May 28, 2009 to address this concern to the parties, directing all MDL litigants (and interested non-MDL parties) to meet with Professor Eric Green, the court-appointed mediator, on June 25, 2009 in order to pursue efforts toward a universal mediation process (a day-long meeting which took place as scheduled, and was attended by all the parties to the instant matter, as well as the United States). (*See* Transcript of 2:15 pm Status Conference, May 28, 2009, 01-CV-12257, at 4:4-16, 5:13-24, 6:1-16 (attached as Ex. 3).[8]

The hearing included responses to the Court from, among others, the United States, California, Dey and Mylan, regarding certain challenges endemic to a universal mediation process. Specifically, the parties addressed some of the uncertainties triggered by the fact that the United States and various states are litigating against defendant manufacturers for the federal share of the same drugs during overlapping time periods, a situation further complicated by disputes regarding such issues as which sovereigns are obligated to shoulder the relator's share of a recovery when state and federal monies are involved. *Id*. at 30-63. Counsel for California, and counsel for Mylan and Dey, specifically addressed the previously described concerns to the

[8] *See also* Transcript of Status Conference held February 12, 2009, at 6 (attached as Ex. 4), in which California explained successful efforts as to eleven defendants with whom mediated settlements were reached under the auspices of Professor Green. Furthermore, California also participated in mediation with Dey, Mylan and Sandoz in April 2009, under the auspices of Professor Green. *See* May 28, 2009 transcript (Ex. 3) at 30:1-11.

Court, see *id*. at 34-35, 39-43, as well as their continued willingness to pursue universal mediation with Professor Green. *See id.* at 38, 51.

California, as the Court is aware, has reached a settlement in principle with named Defendants Schering Plough Corporation and Warrick Pharmaceuticals Corporation. That settlement is set for a final hearing on December 11, 2009, and involves the simultaneous resolution of state and federal claims against Schering and Warrick brought by the relator, Ven-A-Care on behalf of the United States, as well as by the states of California and Florida. As the Court is also aware, the Schering settlement was also reached under the auspices of Professor Green, and among the several challenges raised in the course of efforts to finalize it have been challenges raised by state objectors (both within and outside the MDL) to issues involving the preclusive effect of a settlement which disposes of the United States' claims (as asserted by the relator) across a defined population of drugs. It is inconceivable that these types of difficult and critical issues could have been solved outside of the instant MDL, which, after all, was established to adjudicate pre-trial AWP fraud litigation as well as any and all possible settlement efforts.

The imperative of preserving momentum toward the effective resolution of complex multidistrict litigation via settlement — even when the only settlement prospects are those associated between individual parties (i.e., even in the absence of an MDL-wide initiative toward universal mediation) — has been explicitly identified as a basis on which the JPML should decline to remand individual cases to their courts of origin:

> [W]here the possibility exists that even individual settlement negotiations will be more efficient if facilitated by a judge who is intimately familiar with the general issues and many of the parties, and where in fact the record reflects that settlements are successfully being negotiated, one cannot say that the Panel abused its discretion in refusing to remand.

Patenaude, 210 F.3d at145. The same court found:

> [B]ecause individual settlement negotiations and conferences are ongoing in the plaintiffs' individual cases, and because the transferee court is conducting discovery on issues that affect many asbestos cases, even if not the plaintiffs', coordinated pretrial proceedings have not concluded, and the [remand movants] have not demonstrated a clear and indisputable right to the relief they seek.

Id. at 146.

In light of the importance which this Court has attached to defining a process toward reaching a mediated resolution of MDL 1456 AWP litigation, and in light of the efforts made to date by the parties to the instant case, it would be manifestly counterproductive — and destructive of any momentum toward a mediated settlement — to remand this case to the court of origin. This is a particularly acute concern given the success enjoyed by California and other (former) defendants as a result of their efforts and those of Professor Green in mediation, and the significant resources expended to date in pursuing both individual and group mediations in the California case.

B. Defendants' invocation of earlier remands in the Montana and Nevada cases is of no moment.

Defendants claim that because this Court remanded the Montana and Nevada cases to their courts of origin, remand to the Central District of California "makes eminent sense in this case as well." (Def. Rem. Mot. at 4.) For the reasons set forth above, remanding this case would be flatly inconsistent with the objectives of coordinated multidistrict case supervision as undertaken by this Court, and it would make no sense.

Looking to the Montana and Nevada remands for precedential import is fruitless, because neither case featured the same depth or breadth of cross-cutting issues now common to the various individual cases within MDL 1456 described above. California's claims are brought exclusively under the California False Claims Act, the oldest state false claims act in the country, and one "patterned on [the federal FCA]." *City of Pomona v. Superior Court*, 89 Cal. App. 4th

793, 801 (2001). Given the "very close similarity of California's act to the federal act, it is appropriate to turn to federal cases for guidance in interpreting the act." *Id*. at 802, *Laraway v. Sutro & Co*., 96 Cal. App. 4th 266, 274-275 (2002).

In contrast, both the Montana and Nevada cases featured a number of claims sounding in state-specific causes of action. Specifically, Nevada's case, following this Court's adjudication of defendants' motions to dismiss, included claims brought under the Nevada Deceptive Trade Practice Act, Nevada's Medicaid Fraud statute, as well as common law claims. Montana's case similarly included claims brought under the Montana Unfair Trade Practices & Consumer Protection Act, the Montana Medicaid Fraud Statute, and common law fraud claims. *See In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 321 F. Supp. 2d 187, 194, 208 (D. Mass. 2004).

Lastly, neither case was one in which the respective Attorneys General were litigating in an intervened whistleblower case featuring core allegations central to multiple other government-intervened actions, as is true of the United States' cases and the instant California case. Rather, both Montana and Nevada were represented by private counsel, and there was no relator.

C. Defendants' reference to circuit and district cases from the Ninth Circuit as purportedly dispositive of the remaining issues is devoid of merit.

Defendants cite several district court and Ninth Circuit cases in support of the specious claim that "[t]he issues remaining in the case are case specific and are uniquely suited to adjudication by federal courts sitting in the state of California. . . . Federal district courts in California are familiar with the line of case law that governs the issues that remain and have frequently been reviewing similar questions." (Def. Rem. Mot. at 4-5.) The cases to which Defendants refer for support include *Orthopaedic Hosp. v. Belshe*, 103 F.3d 1491 (9th Cir. 1997), and several of its district and circuit progeny.

Defendants contend in their pending motions for partial summary judgment that, as a matter of law, California's damages claims were not the result of their false and fraudulent AWPs, but rather the result of California's alleged "deliberate execution" of its legal obligation to set reimbursement rates in a manner consistent with the holding of *Orthopaedic*, a case which considered the proper interpretation of Section 30(A) of the Medicaid Act[9] as applied to proposed changes to reimbursement rates by state Medicaid programs. In relevant part, Section 30(A) provides that state Medicaid plans must reimburse providers at rates "consistent with efficiency, economy, and quality of care and [set rates that] are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." In *Orthopaedic*, the Ninth Circuit interpreted Section 30(A) to mean that when setting reimbursement rates for hospital services, Medi-Cal must set rates that "bear a reasonable relationship to efficient and economical hospitals' costs of providing quality services, unless the Department shows some justification for rates that substantially deviate from such costs." *Id*. at 1496. To comply with this mandate, the Court held that Medi-Cal "must rely on responsible cost studies, its own or others, that provide reliable data as a basis for its rate setting." *Id*.

Of course, the real issues in the instant case actually focus on the questions of whether the Defendants had an obligation to report truthful and accurate Average Wholesale Prices for use by California's Medicaid program, and if so, whether the grotesquely and deliberately inflated and fraudulent AWPs they reported on the 394 NDCs at issue caused the submission of millions of false claims and caused hundreds of millions of dollars in overpayments by the

[9] 42 U.S.C. § 1396(a)(30)(A)

biggest state Medicaid program in the country (in terms of both numbers of Medicaid drug recipients and total dollars spent on drugs, in 2004 (the last year at issue in California's case)).[10]

Neither *Orthopaedic*, nor the other cases cited by Defendants on page 5 of their joint motion, have any bearing on the central issues raised in California's case, because they do not address and impart no dispositive guidance in addressing the obligations of those pharmaceutical manufacturers who enjoy vast utilization of their drug products by Medi-Cal providers. Nor do any of the cases cited by Defendants support any dispositive findings as to the falsity of Defendants' reported AWPs.

Defendants point to no authority in support of the proposition that remand is mandated by the Ninth Circuit's supposed familiarity with the government plaintiff. Moreover, "[t]o the extent [a party] is simply seeking to avoid what it predicts will be this Court's application of the correct law, it has never been the case that dissatisfaction with the transferee court's rulings could support remand." *In re Holiday Magic Secs. & Antitrust Litig.*, 433 F. Supp. 1125, 1126 (J.P.M.L. 1977). This concern carries special resonance since this Court's decision in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20 (D. Mass. 2007) has recently been affirmed in all respects by *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 582 F.3d 156 (1st Cir. 2009). "Efforts by parties to use the JPML as

[10] Pharmaceutical Benefits Under State Medical Assistance Programs 2007, published by the National Pharmaceutical Council, Inc. ("NPC"), at B-9, B-11 (attached as Ex. 5). According to its website, NPC is "supported by research-based pharmaceutical member companies, [and] sponsors and conducts research and education projects showing how the appropriate use of pharmaceuticals improves both patient treatment and cost outcomes in the overall health care environment." See http://www.npcnow.org/AboutUs/Mission.aspx

a substitute for appellate review, by seeking premature remand, have been uniformly rejected." Manual for Complex Litigation (Fourth) § 20.133 (2008), fn. 673.[11]

CONCLUSION

In denying a motion for suggestion of remand, the court in *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.,* 498 F. Supp. 2d 25, 38 (D.D.C. 2007) concluded that "[t]his Court's familiarity with the issues in this case — a case which by now encompasses a voluminous docket — as well as the many related issues in the other cases in this MDL, indicates that it would be much more efficient to proceed to summary judgment motions in this Court rather than to ask the transferor court to play catch-up." For all the reasons set forth in the preceding discussion, the same conclusion is appropriate here. This Court should deny Defendants' motion for a suggestion of remand to the Central District of California.

[11] The odd timing of Defendants' motion, filed coincident with the parties' filing of their motions for summary judgment but seeking remand without this Court's adjudication of those motions, could be related to the fact that orders issued by a federal transferee court remain binding once the case is sent back to the transferor court, *see* Manual for Complex Litigation § 20.133; 28 U.S.C. § 1407(b) ("the judge ... to whom such [MDL] actions are assigned .... may exercise the powers of a district judge in any district").

REQUEST FOR ORAL ARGUMENT

Pursuant to Local Rule 7.1(d), Plaintiff requests oral argument on this motion.

Dated: December 9, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on December 9, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Nicholas N. Paul
NICHOLAS N. PAUL